PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference H27497CNO1FD	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP 03/11211	International filing date *(day/month/year)* 11.09.2003	Priority date *(day/month/year)* 11.09.2003
International Patent Classification (IPC) or both national classification and IPC A61L31/12		
Applicant SEFT HOLDING SA et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
03.08.2004	24.09.2004
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Böhm, I Telephone No. +31 70 340-1050

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 03/11211

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-10 as originally filed

Claims, Numbers

1-15 as amended (together with any statement) under Art. 19 PCT

Drawings, Sheets

1/1 as originally filed

Drawings, Figures

1-5 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-15
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-15
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-15
	No:	Claims	

2. Citations and explanations

   see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1.
The amendments filed with the International Bureau under Article 19(1) do not introduce subject-matter which extends beyond the content of the application as filed, contrary to Article 19(2) PCT. The amendments concerned are the following:

The features of former claim 3 are introduced in the independent claim 1, therefore a restriction on the subject-matter on former claim 3 was made.

Reference is made to the following documents (D1-D2) :

D1: US 20020087056 A
D2: US 20020102185 A

The present application meets the requirements of Article 33(1) PCT, because the subject-matter of claims 1-15 is new in the sense of Article 33(2) PCT.

2.
D1 discloses an analytic monitoring device comprising a plurality of needles adapted to pierce skin. The needle can be provided with a bevel. The needles are small-scaled with sufficient rigidity and durability. The small size also reduces the pain associated with piercing the subject's skin. The needles can be made by small-scaled molding of suitable plastics, such as polyetheretherketone (PEEK). The polymer can be filed with a reinforcing substance, such as 10-40% filled with glass or carbon fiber. (see paragr. 9,29.46,48)

3.
D2 discloses needles for collecting samples coated with a synthetic resin coating of PEEK for reducing chemical adsorption on the needle's surface. PEEK is a synthetic resin having high chemical resistance and mechanical strength. PEEK is an organic material, and accordingly shows a chemical adsorptive property. In addition, PEEK shows a superior resistance to various chemicals. (see paragr. 16,17,25,26)

The idea of having reinforcement material in the polymer, which forms the needle is known from D1, such as glass or carbon fibers, but neither D1 nor D2 discloses reinforcement wires embedded throughout the length of hollow body in the polyaryletherketone polymer, which constitute the needle.
The needle itself, injection syringe, the recipient connector containing also said needle are therefore novel vis-à-vis the cited prior art

II) Inventive step

The subject-matter of claims 1-15 has been considered as being inventive due to the following reasoning based on the cited prior art (D1):

4.
D1 represents the most **relevant prior art** and discloses an analytic monitoring device comprising : a plurality of needles, [...], the needles can be provided with a bevel. The needles can be made by small-scaled molding of suitable plastics such as polyetheretherketone. The polymer can be filled with a reinforcing substance, such as glass or carbon fiber. (see paragr. 9,29,48, fig 7C)

5.
The **problem** underlying the present application seeks to solve is the provision of a needle for injection which is not only sterile and sterilizable, but also apyrogenic and without suffering any deformation or damage to their chemical and mechanical properties, providing chemical resistance and mechanical strength.

6.
The **solution** proposed in the present application is a needle made of plastic, characterized with the features of claim 1.
Another object of the present application is the provision of an injection syringe (claims 8-10) and furthermore yet another object is a connector for recipients (claims 11-15).

7.
The technical feature common to these 3 products is the needle made of a polyarylethercetone polymer (formula 1) constituted of a cylindrical body having at least one end (respectively claim 1) or both end bevelled (respectively claim 7).
However this common feature is known as a feature of solutions to the same principal problem disclosed in the prior art.

8.

The effect:

The inventive concept is based on the combination of a chemical resistance and mechanical strength providing polymer, such as PEEK as the polymer material, which is sterilizable at high temperature maintaining the chemical and mechanical properties in combination with reinforcement wires throughout the length of the needle, which provides mechanical rigidity (for penetration into the skin).

The combination of the PEEK-polymeric material with reinforcement wires has not been suggested in the prior art and has not been obvious for a skilled person in the art in order to solve the problem posed.

Therefore the subject-matter of claims 1-15 of the present application involves an inventive step